

Current practice of first-line treatment strategies in patients with critical limb ischemia

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Objective: Critical limb ischemia (CLI) is growing in global prevalence and is associated with high rates of limb loss and mortality. However, a relevant gap of evidence about the most optimal treatment strategy still exists. The aim of this study of the prospective, multicenter First-Line Treatments in Patients With Critical Limb Ischemia (CRITISCH) registry was to assess the current practice of all first-line treatments strategies in CLI patients in German vascular centers.

Methods: Between January 2013 and September 2014, five first-line treatment strategies—endovascular revascularization (ER), bypass surgery (BS), femoral/profundal artery patchplasty (FAP), conservative treatment, and primary amputation—were determined among CLI patients in 27 vascular tertiary centers. The main composite end point was major amputation or death, or both, during the hospital stay. Secondary outcomes were hemodynamic failure, major adverse cardiovascular and cerebral events, and reintervention. Univariate logistic models were additionally built to preselect possible risk factors for either event, which were then used as candidates for a multivariate logistic model.

Results: The study included 1200 consecutive patients. First-line treatment of choice was ER in 642 patients (53.4%), BS in 284 (23.7%), FAP in 126 (10.5%), conservative treatment in 118 (9.8%), and primary amputation in 30 (2.5%). The composite end point was met in 24 patients (4%) after ER, in 17 (6%) after BS, in 8 (6%) after FAP, and in 9 (8%) after conservative treatment ($P = .172$). The highest rate of in-hospital death was observed after primary amputation (10%) and of hemodynamic failure after conservative treatment (91%). Major adverse cardiovascular and cerebral events developed in 4% of patients after ER, in 5% after BS, in 6% after FAP, in 5% after conservative treatment, and in 13% after primary amputation. The reintervention rate was 8%, 14%, 6%, 5%, and 3% in each group, respectively. In the multivariate regression model, coronary artery disease (odds ratio [OR], 2.96; 95% confidence interval [CI], 1.42-6.17) and previous myocardial infarction (PMI) <6 months (OR, 3.67, 95% CI, 1.51-8.88) were identified as risk factors for the composite end point. Risk factors for amputation were dialysis (OR, 3.31, 95% CI, 1.44-7.58) and PMI (OR, 3.26, 95% CI, 1.23-8.36) and for death, BS compared with ER (OR, 3.32; 95% CI, 1.10-10.0), renal insufficiency without dialysis (OR, 6.34; 95% CI, 1.71-23.5), and PMI (OR, 7.41; 95% CI, 2.11-26.0).

Conclusions: The CRITISCH registry revealed ER as the most common first-line approach in CLI patients. Coronary artery disease and PMI <6 months were independent risk factors for the composite end point. Special attention should be also paid to CLI patients with renal insufficiency, with or without dialysis, and those undergoing BS. (J Vasc Surg 2015;62:965-73.)

Critical limb ischemia (CLI) is the most severe type of peripheral arterial vascular disease and remains a substantial cause of death and health costs: the 6-month mortality rate accounts for 20%, and the inpatient hospital treatment averages €20,000 at 1 year.¹ In the PAD Awareness, Risk and Treatment: New Resources for Survival (PARTNERS)

study, which included patients aged 50 to 70 years with history of smoking or diabetes, the overall proportion of CLI patients was 29%.² Considering that the population ages and the metabolic syndrome is growing in global prevalence, the clinical and socioeconomic effect of the disease will be magnified in the near future.¹⁻³

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A list of the First-Line Treatments in Patients With Critical Limb Ischemia (CRITISCH) collaborators is provided in the [Appendix](#).

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Nevertheless, there is still a relevant lack of evidence for the most optimal treatment strategy in CLI. This can be explained due to the involvement of different disciplines,⁴ the lack of high-level evidence,³ and the rapid material evolution in the endovascular era.^{3,4} The first results of Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL-2) and Best Endovascular vs Best Surgical Therapy in Patients With Critical Limb Ischemia (BEST-CLI) trials are anticipated after 2018, and whether their results will cover all aspects of the disease remains controversial.⁵

At present, the durability of the endovascular approach in CLI patients is a matter of debate, and a current systematic review revealed that the endovascular approach is not inferior to bypass surgery (BS) for limb salvage in those patients.⁶ Hence, decision making depends mostly on the physician's expertise, and little is known about which approach accounts as the first-line treatment strategy in CLI patients among the vascular centers.

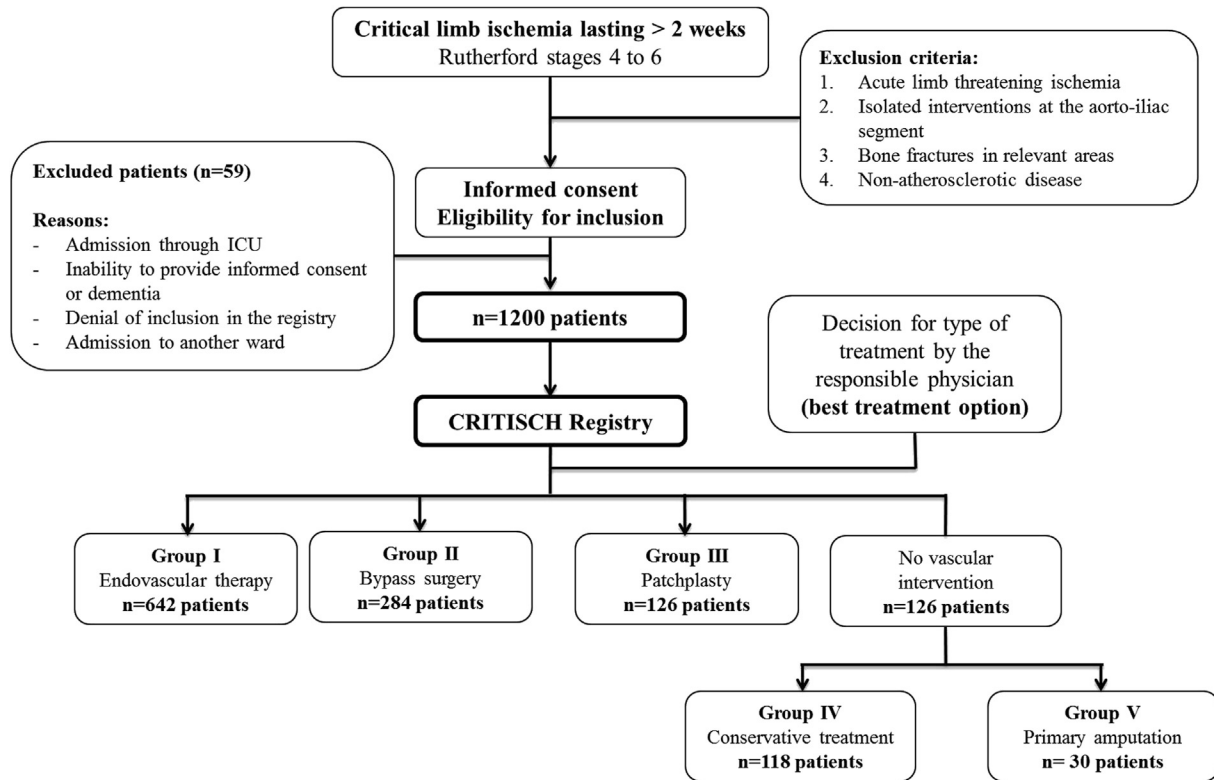


Fig 1. Schematic overview of recruitment procedure in First-Line Treatments in Patients With Critical Limb Ischemia (CRITISCH) registry. *ICU*, Intensive care unit.

To inform this debate, we assessed the current practice in Germany, in the framework of the real-world, multicenter, prospective First-Line Treatments in Patients With Critical Limb Ischemia (CRITISCH) registry. In particular, we analyzed physicians' preferences and described the respective outcomes of each approach. In this report we present the early results of the CRITISCH registry with the focus on strategy-specific differences and the detection of risk factors for poor in-hospital outcomes.

METHODS

The study was performed in accordance with the principles in the Declaration of Helsinki. Ethical approval was obtained from all participating centers before patients were recruited. All patients gave written informed consent.

Study design and patients. A summary of the recruitment procedure is illustrated in Fig 1, and Supplementary Table I (online only) provides an overview of the study assessment requirements. The inclusion criterion in CRITISCH registry was the diagnosis of CLI lasting >2 weeks. To avoid any bias for possible previous vascular interventions, only patients with new-onset CLI at the time of presentation and not these with ongoing symptoms after the last previous vascular intervention at the index limb were included. CLI was defined as an ankle-brachial index (ABI) ≤ 0.40 or pain at rest, or both, with or without on-going degrees of tissue loss in

the presence of peripheral artery disease (Rutherford classification stages 4-6).⁷ Only one leg per patient was assessed. The study excluded patients with acute limb-threatening ischemia (embolic or thrombotic), isolated iliac interventions, bone fractures at the index leg, non-atherosclerotic disease (eg, arteritis), and documented hypercoagulable status (Fig 1).

The type of treatment was left exclusively to the discretion of the treating physician (best treatment strategy). The different first-line treatment strategies were classified into five groups:

Group I included patients undergoing all types or techniques of solely endovascular revascularization (ER). ER was considered any intervention where a percutaneous endovascular technique alone was used. In case of technical failure to cross the lesions, the first-line treatment remained the endovascular approach, and any further procedure by means of BS was considered as a reintervention.

Group II consisted of patients undergoing BS using all possible types of conduit.

Group III included patients undergoing only femoral/profundal artery patchplasty (FAP), with or without a concomitant distal endovascular intervention, by means of a hybrid procedure.

Group IV included patients treated conservatively.

Group V were those undergoing a primary major amputation (PMA).

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